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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,680	04/16/2004	Richard A. Weltzin	06132/091001	1402

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EXAMINER	
SNYDER, STUART	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,680	WELTZIN ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and Seq. ID NO:244 in the reply filed on 2/14/2007 is acknowledged. The traversal is on the ground(s) that searching several other amino acid sequences or SEQ ID NO:2 (full-length vaccinia virus) would not place an undue burden on the Examiner. Applicant also points to MPEP 803.04, which discusses a reasonable number of independent and distinct sequences to be examined in a single application. This is not found persuasive because, after careful analysis, it is determined that the structural similarities between SEQ ID NOs: 244, 166, 194, 220, 224, 254, 282, 284, 292, 318 remain patentably distinct and will not be rejoined unless the elected sequence is found to be novel over the prior art. With regards to SEQ ID NO:2, should applicant have wished to elect SEQ ID NO:2, applicant had sufficient opportunity to do so but chose not to so elect. Therefore, because each of the claimed SEQ ID NOs: 166, 194, 220, 224, 254, 282, 284, 292, and 318 requires a separate and divergent search in the prior art due to the unique structural features of each sequence, the requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to, *inter alia*, an isolated and cloned vaccinia virus that is a derivative of a viral component of DryVax® (New York City Board of Health strain, Wyeth Laboratories).

The written description rejection is made because the claims are interpreted as being drawn to a genus of products recited as "substantially identical to", "comprises a nucleotide sequence that is at least 70% [80%, 90%, 95%, or 98%] identical to the sequence of SEQ ID NO:1 or SEQ ID NO:2", "hybridizes to the sequence of SEQ ID NO:1 or SEQ ID NO:2, a fragment of SEQ ID NO:1 or SEQ ID NO:2, or the complement of SEQ ID NO:1 or SEQ ID NO:2, under highly stringent conditions", and "said fragment [of the viral DNA] comprises a coding sequences selected from the group consisting of SEQ ID NOs:3-471 (odd numbers) [or encodes a polypeptide selected from the group consisting of SEQ ID NOs:4-472 (even numbers)], or the complement thereof". The applicable standard for the written description requirement can be found in MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609; Vas- Cath Inc. v. Mahurkar, 19 USPQ2d 1111; and University of Rochester v.

G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004). To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the factors present in the claims is the nucleotide sequence of cloned vaccinia viruses ACAMBIS 1000 (SEQ ID NO:1) or ACAMBIS 2000 (SEQ ID NO:2) and functional characterization including "plaque morphology, yield in MRC-5 cells, restriction endonuclease mapping patterns, the formation of cutaneous pocks in rabbits, mouse neurovirulence and induction of protective immunity in mice" (see lines 20-24, page 12 of specification). There is no disclosure of any particular portion of the structure that must be conserved in order to be "substantially identical to SEQ ID NO:1 or SEQ ID NO:2", "at least 70% [or up to 98%] identical to SEQ ID NO:1 or SEQ ID NO:2", or "hybrid[izable] to the sequence of SEQ ID NO:1 or SEQ ID NO:2...under highly stringent conditions" and are shown to correlate with the desired phenotypic properties described above.

Accordingly, in the absence of sufficient recitation of the correlation between specific viral sequences and distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. A definition by function alone does not suffice to sufficiently describe a coding

sequence because it is only an indication of what the genes do, rather than what they are and the specific sequences responsible for the desired properties. Eli Lily, 119 F.3 at 1568, 43 USPQ2d at 1406.

The court clearly states in Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented what is claimed. As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of variants, derivatives or structural equivalents of either ACAMBIS 1000 or 2000 that inherently possess the desired properties recited in the specification. Given that the specification has only described the structure and function of ACAMBIS 1000 and 2000 (SEQ ID NOs:1-2) without reference to the specific sequences within the virus that confer the functions, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "substantially identical to...". There is no definition of this phrase in the specification nor is there a generally accepted definition for this phrase in the art.

Claim 7 recites the phrase "highly stringent conditions". The specification discusses stringency conditions but gives two different examples of "high stringency conditions"—see and compare paragraph 2 and 3, page 5. Thus, a skilled artisan is not informed by the specification which of the two different examples teaches "highly stringent conditions" of claim 7.

Claims 2-13 depend on claim 1; claim 8 depends on claim 7. Thus, claims 1-13 are properly rejected 35 U.S.C. 112, second paragraph, as being indefinite.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dumbell and Richardson (1993). Claims 1-11 are drawn to a vaccinia virus molecular clone that has certain phenotypic characteristics and was derived from DryVax®, as mentioned above. Claims 1-11 describe the invention in terms of percent sequence identity and the ability of other members of the genus to hybridize to either of the full-length sequences or fragments thereof. Dumbell and Richardson describe several buffalopox viruses isolated in India between 1985 and 1987 that have inherent properties that anticipate the claims of the instant application. Later sequence analysis of several of the genes of the isolated Orthopox viruses (see Singh, et al. 2006) clearly show that a high degree of sequence identity amongst the various Orthopox viruses (see especially table 2c). For example, comparing the rabbitpox and buffalopox D8L-like protein, there was less than 1% difference between the two sequences (figure 2c); V181A, E248D, and F293L were the only point mutations observed in the 304 amino acids of the full-length protein. A comparison of the same gene with vaccinia virus strain WR and horsepox virus homologues to the protein encoded according to SEQ ID NO:244 shows greater than 97% amongst the homologues with the vaccinia and horsepox virus homologues possessing greater than 99% sequence identity to that of SEQ ID NO:244 differing from SEQ ID NO:244 by only one amino acid. In absence of teaching to the contrary by Applicant, it is clear that the DNA encoding the buffalopox protein would inherently possess all of the properties of the invention as taught by

Applicants' specification and delineated in the claims. Thus, by the criteria claimed for the invention of the instant application, the buffalopox viruses anticipate, or in the alternative are obvious over, the invention claimed in the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

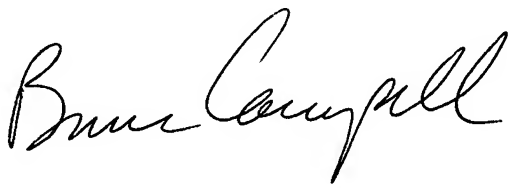
4. Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 7115270. Although the conflicting claims are not identical, they are not patentably distinct from each other because the vaccinia virus clone used as an example in the instant application is identical to that of the patent (see specification page 3, line 14 and following) and one of several clones derived from DryVax® that would meet all of the limitations of the claims.

5. Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6723325. Although the conflicting claims are not identical, they are not patentably distinct from each other because the vaccinia virus clone used as an example in the instant application is identical to that of the patent (see specification page 3, line 14 and following) and one of several clones derived from DryVax® that would meet all of the limitations of the claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS



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